UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,010	02/02/2001	Gregory Bruce Wilson	0179/61248-A/JPW/BJA	7419

7590 05/02/2002

Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER
LI, BAO Q

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 05/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,010	WILSON ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02/28/2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12-24 and 28-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9, 12-24 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to the Amendment

This is a response to the amendment, paper No. 7, filed 03/13/01. Claims 10, 11, and 25-27 are canceled. Claims 1, 2, 20 and 24 are amended. New claims 30-31 are added. Claims 1-9, 12-24, 28-29 and 30-31 are pending before the examiner.

Please note any ground of rejection that has not been repeated is removed.

The text of those sections of Title 35,US.Code not included in this section can be found in a prior office action.

Claim Objection

The amendment filed on paper No. 10, 09/17 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: "an antigen-specific" cited in claims 1 and 2.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Claims 1-9, 12-24 and 28-31 are still rejected under 35 US code § 112 second paragraph on the similar ground as previous states in the Office Action mailed 10/17/01.

Regarding to the rejection on Applicants 'failing to particular point out which specific transfer factor clams 1-2, Applicants attempted to overcome the rejection by amending the transfer factor is an antigen-specific transfer factor. Therefore, Applicants assert that the rejection should be withdrawn because of this amendment. Applicants' argument is fully considered. However, it is not persuasive because the particular structure of the claimed transfer factor produced by the infection of HSV-6A or HSV-6B are not defined. Furthermore, Applicants' argument based on the amendment is also moot because of the new ground rejection. Applicants are reminded if Applicants wish to claim a particular transfer factor against a particular antigen as a product claim, a precise structure of the transfer factor should be claimed. Therefore, the rejection is maintained and it affects the dependent claims 3-9, 12-24 and 28-31.

Regarding to the rejection of claims 13-18 that the cited "subject" is not defined. Applicant argue that the term "subject" can be clearly understood by the one of skill in the art as a mammal, especially as cited in the specification as a human being. In response to applicant's argument, it is noted that the features upon which applicant relies (i.e., a human as a subject for the treatment) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please amend the claim accordingly.

Regarding to the rejection of the undefined "abnormality" cited in the claims 16-18. Applicants assert that cited "abnormality" is a disease, such as multiple sclerosis and chronic fatigue syndrome as cited in the specification. In response to applicant's argument, it is noted that the features upon which applicant relies (i.e. multiple sclerosis and chronic fatigue syndrome) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please amend the claim accordingly.

Regarding to the rejection of claim 24, Applicants try to overcome the rejection by amending the claim. Applicants further argue that the characteristic of the carrier is not a latent characteristic , but rather a subset of carriers. The claim is directed to that subset of the carrier. In response to Applicants' argument, the recitation of "capable' should be amended to reflect an ability that the carrier has because the word "capable" has a meaning of a latent characteristic.

Claim Rejections - 35 USC § 102

Claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. 102(b) over the prior art De Vinci et al. (Biotherapy 1996, Vol. 9, pp. 87-90) on the similar ground described in the previous Office Action.

Applicants argue that De Vinci et al. do not teach the transfer factor (TF) is an antigen specific against the specific species of human herpesvirus-6 and method of using the same. in contrast, applicants' claimed invention is directed to a transfer factor induced by human herpesvirus-6A or 6B.

Applicants' argument is respectfully considered, however, it is not found persuasive. Because the transfer factor taught by De Vinci et al. is produced by the infection of human herpesvirus-6, which exhibits the same activity as it is claimed in the instant Application. There is not clue to tell that these two transfer factors are structurally and functionally different.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objection made. Further, they do not show how the amendments avoid such references or objections. Therefore, the rejection is maintained

Applicants reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. 102(b) over the prior art Ablashi et al. (Biotherapy 996, Vol. 9, pp. 81-86) on the similar ground described in the previous Office Action.

Applicants argue that Ablashi et al. do not teach the transfer factor (TF) is an antigen specific against the specific species of human herpesvirus-6 and method of using the same. in contrast, applicants' claimed invention is directed to a transfer factor induced by human herpesvirus-6A or 6B.

Applicants' argument is respectfully considered, however, it is not found persuasive. Because the transfer factor taught by Ablashi et al. is produced by the infection of human herpesvirus-6, which exhibits the same activity as it is claimed in the instant Application. There is not clue to tell that these two transfer factors are structurally and functionally different.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objection made. Further, they do not show how the amendments avoid such references or objections. Therefore, the rejection is maintained.

Applicants reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claims 1-2, 5-9, 12-13, 17-24 and 28-31 are still rejected under 35 U.S.C. 102(b) over the prior art Wilson et al. (US Patent No. 4,816,563) on the similar ground described in the previous Office Action.

Applicants argue that Wilson et al. do not teach the transfer factor (TF) is an antigen specific against the specific species of human herpesvirus-6 and method of using the same. in contrast, applicants' claimed invention is directed to a transfer factor induced by human herpesvirus-6A or 6B.

Applicants' argument is respectfully considered, however, it is not found persuasive. Because the transfer factor taught by Wilson et al. is produced by the infection of human herpesvirus, which exhibits the same activity as it is claimed in the instant Application. There is not clue to tell that these two transfer factors are structurally and functionally different.

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty, which he or she thinks the claims present in view of the state of the art disclosed by the reference cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Therefore, the rejection is maintained.

Applicants reminded that The Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claim Rejections - 35 USC § 103

Claims 1-9, 12,-24, 28-29 and 30-31are still rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Patent Nos. 4,816, 563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) in view of Challoner et al. (P. N. A. S. 1995, Vol. 92, pp. 7440-7444).

Applicants argue that although Wilson et al. (Patent Nos. 4,816, 563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) all teach that the method for extracting the transfer factor (FT) from viral or other infectious agent infected animal and the method for using the FT enriched milk or cellular extract to treat the chronic fatigue syndrome (CFS) and Challoner et al. suggest to use HHV-6 specific FT for treating multiple sclerosis (MS), it would not be obvious to combine the teachings of Challoner et al. and Ablashi et al. or Wilson.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the

teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, even Applicants acknowledged that Wilson et al. (Patent Nos. 4,816, 563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) all teach that the method for extracting the transfer factor (FT) from viral or other infectious agent infected animal and the method for using the FT enriched milk or cellular extract to treat the chronic fatigue syndrome (CFS) and Challoner et al. suggest to use HHV-6 specific FT for treating multiple sclerosis (MS). Therefore, the rejection is maintained.

New Grounds of Rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2 are also rejected in that the metes and bonds of " an antigen specific" are not defined. Although the claims are interpreted in light of the specification, the speciation, however, fails to define which antigen is referred in the claims. Because HSV-6A and HSV-6B consist of many antigens, the claims should point out which antigen is intended in the said claim.

Claim 30 is unclear in that the metes and bonds of " a mammal" are not defined. Because there are so many mammals in the art, is killer wile intended? This affects the dependent claim 31.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li
May 1, 2002

ALI R. SALIMI
PRIMARY EXAMINER